In the United States Court of Federal Claims Office of special masters No. 21-2030V

Paul A. Green, Law Office of Paul Green, Pasadena, CA, for Petitioner.

Bridget Corridon, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION¹

On October 18, 2021, Jose Wilson Rojas Guzman filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").² Petition (ECF No. 1) at 1. Petitioner alleges that he experienced anaphylaxis, rash, autoimmune hepatitis, and/or exacerbation of hepatitis after receipt of a trivalent influenza ("flu") vaccine on October 17, 2018. *Id*.

A dispute has arisen between the parties as to whether Petitioner has established a proper vaccine-related injury. *See* Respondent's Status Report, dated Nov. 14, 2022 (ECF No. 23) ("Rep.") at 1. I therefore directed Petitioner to file a brief explaining the nature of the alleged injury, with reference to all medical record evidence supporting his contentions. *See* non-PDF Order, dated Nov. 28, 2022. In response, Petitioner has filed a brief arguing that he suffered

¹ Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id*.

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. §§ 300aa.

anaphylaxis, a rash, autoimmune hepatitis, and/or an exacerbation of hepatitis as a result of his trivalent flu vaccination. *See generally* Petitioner's Brief, dated Feb. 28, 2023 (ECF No. 24) ("Br."). The matter is now ripe for resolution—and as explained below, because I do not find preponderant support for Petitioner's injury contention, the matter is appropriately dismissed.

I. Brief Factual Summary

Mr. Guzman was born on November 26, 1980. Pet. at 1. His past medical history was significant for esophagitis, GERD, allergic rhinitis, steatosis of the liver, hydrocele, tension headaches, and duodenitis. Ex. 1 at 3. Lab results from April 30, 2013, showed that Petitioner possessed reactive antibodies to hepatitis A, suggesting a prior infection and/or degree of immunity to future infection. Ex. 2 at 346.

On October 17, 2018, Petitioner received a flu vaccine at Centinela State Prison, California (where it appears he was incarcerated). Ex. 2 at 3. A week later, on October 24, 2018, he presented to Palo Verde Hospital with flu-like symptoms, reporting that "he had been sick for almost two weeks, progressively becoming worse on the day of admission." Ex. 1 at 2. This would suggest an onset predating vaccination—although he further indicated that he had been experiencing "fever and chills for about three days." *Id.* Petitioner's treating physician documented a "rash on the dorsum of the ankle and the middle of the leg on both [the] left and right," but there is no evidence in the medical records to suggest that Petitioner received any treatment pertaining to such rash. *Id.* at 4.

Before being discharged on October 30, 2018, back to Centinela State Prison, Petitioner was seen by his primary care physician, Adolfo Paglinawan, M.D., on October 27, 2018. Ex. 1 at 18. Dr. Paglinawan examined Petitioner's lab results and diagnosed Petitioner with right upper lobe pneumonia, iron deficiency amenia, and hepatitis C. *Id.* At the time, Dr. Paglinawan did not believe that Petitioner's pneumonia resulted from a coccidioidomycosis³ infection, the presence of which was based on old test results. *Id.* Dr. Paglinawan also noted that Petitioner had elevated liver enzymes but attributed this to Petitioner's hepatitis C infection. *Id.* at 3. Later (and contrary to earlier speculation), test results interpreted on November 1, 2018 (based on samples drawn during his initial hospital visit) revealed that Petitioner had "...undergone a coccidioidal infection liekly [sic] of relatively recent onset." Ex. 3 at 135. As a result, subsequent medical records referred to Petitioner's hospitalizing illness as attributable to coccidioidomycosis. *See* Ex. 2 at 41, 48, 52, 55–56.

Disseminated disease may involve any organ, most often the skin, bones, and joints, or meninges." *Coccidioidomycosis*, Dorland's medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=10315&searchterm=coccidioidomycosis (last visited July 17, 2023).

ranges from pneumonia to chronic pulmonary involvement with formation of nodules or peripheral cavitation.

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³ "Coccidioidomycosis" is defined as an "infection by spores of Coccidioides imitis or C.posadasii, seen primarily in southwestern United States, northwestern Mexico, and parts of Central and South America. It is often asymptomatic; when symptomatic it usually presents as a self-limited upper respiratory disorder. More severe pulmonary infection

There is a several-month records gap, with no evidence of any follow-up issues or concerns. Then, on January 3, 2019, Mr. Guzman again visited the Palo Verde Hospital complaining of sharp chest pain on his right side which had been ongoing for two days. Ex. 3 at 15. Petitioner was discharged later that day. *Id.* at 7. It was noted that Petitioner had a history of skin rash and nonspecific skin eruption, but no rash was noted during this hospital stay. *Id.* at 4, 21. And the records of this visit note no other issues, and do not reference or mention Petitioner's post-vaccination issues from the fall. *Id.* at 3, 11.

The next medical record submitted in this case is from September 2020, at which time Petitioner's treating physicians at Valley State Prison noted that Petitioner's hepatitis C was chronic and ongoing for at least four years. Ex. 2 at 46. Petitioner's records in fact consistently deem his hepatitis C as an ongoing condition from May 2020–October 2020. *See Id.* at 41, 45, 48, 59, 63, 77, 123, 126.

II. Parties' Arguments

Respondent maintains that the medical record as filed fails to substantiate the existence of a vaccine-related injury. Rep. at 1. Respondent not only notes that there is no diagnosis of autoimmune hepatitis or anaphylaxis in the medical records, but Petitioner also had documented hepatitis and mildly elevated liver enzymes *prior* to vaccination, even though his claim seems to identify these as part of his injury. *Id.* Moreover, Respondent argues that there is a lack of evidence in the medical records to support a significant aggravation of Petitioner's preexisting hepatitis C infection. *Id.* at 1–2. And the rash experienced by Petitioner, and observed close in time to vaccination, does not meet the statutory "severity" requirement, since it has not been shown to have persisted for six months (and may have occurred prior to vaccination as well). *Id.* at 2; Section 11(c)(1)(D)(i).

Petitioner maintains that he endured anaphylaxis, a rash, autoimmune hepatitis, and/or an exacerbation of hepatitis. Br. at 1. Petitioner points to a lab test performed to rule out the presence of autoimmune hepatitis to support his claim. *Id.* at 2. He also relies on his VAERS report where he indicated that he felt bad a couple hours after a flu shot and experienced fever, body aches, a headache, difficulty breathing, and red spots on his feet that caused pain when he walked. Br. at 3. Petitioner then attempts to provide some medical authority linking a variety of vaccines, including the trivalent flu vaccine, to autoimmune hepatitis. *Id.* at 2–5. But this section of his filing lacked any clear citation to any exhibit except for one sentence indicating the timeframe in which flu vaccination can cause autoimmune hepatitis. *Id.*

ANALYSIS

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id*.

In particular, a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.*, a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

As Petitioner's filing relevant to the present inquiry makes clear, he seeks to argue that his October 2018 vaccination caused anaphylaxis, a rash, autoimmune hepatitis, and/or an exacerbation of hepatitis. Br. at 1. But the medical records filed in this case do not reveal he experienced any of these injuries.

First, Mr. Guzman has not shown by a preponderance of evidence that he has suffered from anaphylaxis⁴ or autoimmune hepatitis⁵. But as Respondent points out, there is no medical diagnosis of autoimmune hepatitis or anaphylaxis to be found at all in Petitioner's records. Rep. at 1. There is also nothing in the record to indicate that Petitioner arguably experienced either of these conditions.⁶ Petitioner's only reference to the record is a test to *rule out* autoimmune hepatitis,

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⁴ "Anaphylaxis" is defined as "a type I hypersensitivity reaction in which exposure of a sensitized individual to a specific antigen or hapten results in urticaria, pruritus, and angioedema, followed by vascular collapse and shock and often accompanied by life-threatening respiratory distress." *Anaphylaxis*, Dorland's medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=2577 (last visited July 17, 2023).

⁵ "Autoimmune hepatitis" is defined as "an autoimmune disease of the liver, occurring more often in females, characterized by circulating autoantibodies and hypergammaglobulinemia; it is associated with extrahepatic complaints such as malaise, fever, and arthralgia. Type 1 is characterized by antinuclear and anti–smooth muscle antibodies; type 2 is less common and is characterized by antibodies against the microsomal antigen of liver and kidney." *Autoimmune hepatitis*, Dorland's medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=80608&searchterm=autoimmune+hepatitis (last visited July 11, 2023).

⁶ Petitioner of course cannot succeed by providing a self-diagnosis, nor do his uncited medical claims about a relationship between autoimmune hepatitis and vaccines (including trivalent influenza) prove persuasive. At best, he offers one item purporting that autoimmune hepatitis "has been known" to manifest seven to thirty days after receipt of the flu vaccine. Br. at 4; T. Sasaki et al., *Autoimmune Hepatitis following Influenza Virus Vaccination*, 97 Med. 1, 5 (2018), filed as Ex. 7 on Feb. 28, 2023 (ECF No. 25-2). But Petitioner's failure to show *he* may have experienced autoimmune hepatitis renders irrelevant other scientific evidence linking vaccination to it. *Althen*, 418 F.3d at 1278; *Andreu ex re. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375—77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

which it in fact did. Ex. 3 at 112, 132. And Petitioner's VAERS report⁷ (in which he documented his purported symptoms), cannot *by itself* prove preponderantly that Petitioner suffered an injury.

Second, Petitioner has not proven preponderantly that his hepatitis was aggravated by the vaccination. Instead, the record indicates that Petitioner was already, and for some time, suffering from prior hepatitis infections when he received the flu vaccine. Ex. 2 at 346. And Petitioner's hospital stay, as noted by his medical records following diagnosis, was a result of coccidioidomycosis. Ex. 2 at 41, 49, 63. Petitioner was also diagnosed with hepatitis C while treaters were in the process of diagnosing him, yet none attributed his hospital stay to hepatitis, but instead to coccidioidomycosis. Ex. 1 at 53; Ex. 3 at 115, 135. And no other evidence suggests his hepatitis likely worsened post-vaccination. See Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three Whitecotton factors for claims regarding aggravation of a Table injury with the three Althen factors for off table injury claims to create a six-part test for off-Table aggravation claims); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part Loving test).

Finally, Petitioner's rash as a possible vaccine-related injury does not meet the Act's severity requirement. See Section 11(c)(1)(D)(i). Id. at 5–6. That provision requires a petitioner to prove that her alleged vaccine-related illness, disability, injury, or condition either: lasted longer than six months, resulted in death, or "resulted in inpatient hospitalization and surgical intervention." Id. But the rash observed in October 2018 was not later shown to persist or continue to exist as of April 2019. In fact, as Respondent points out, by January 2019 Petitioner did not report any ongoing rash, but only of past rash symptoms. Ex. 3 at 4, 21.

I am aware that dismissal of a case is a difficult consequence to bear. But my review of the existing record does not suggest this claim is viable—and even after being provided the chance to show why the claim should be permitted to go forward, Petitioner has not done so.

CONCLUSION

Under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on his claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1). In this case, there is insufficient evidence in the record for Petitioner to meet his burden of proof. Therefore, Petitioner's claim cannot succeed and must be dismissed. Section 11(c)(1)(A).

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⁷ The Vaccine Adverse Event reporting system ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers.hhs.gov/about html (last visited July 17, 2023). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. *See generally Carda v. Sec'y of Health & Hum. Servs.*, No. 14-191V, 2017 WL 6887368, at *6 (Fed. Cl. Spec. Mstr. Nov. 16, 2017).

Accordingly, I hereby **DISMISS** Petitioner's case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.⁸

IT IS SO ORDERED.

/s/ Brian H. Corcoran Brian H. Corcoran Chief Special Master

⁸ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.